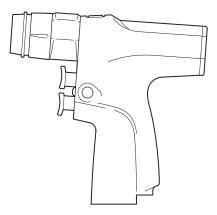


# System 8 Dual Trigger Rotary Handpiece

REF 8205-000-000

**Instructions For Use** 

R<sub>x</sub> ONLY ( € 0197



ENGLISH (EN)

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# Introduction

This instructions for use manual contains information intended to ensure the safe, effective, and compliant use of your product.

Keep and consult this reference manual during the life of the product.

**NOTE:** The user and/or patient should report any serious product-related incident to both the manufacturer and the Competent Authority of the European Member State where the user and/or patient is established.

### Audience

This manual is intended for in-service trainers, physicians, nurses, surgical technologists, and biomedical equipment technicians.

## Conventions

The following conventions are used in this manual:

 A WARNING highlights a safety-related issue. ALWAYS comply with this information to prevent patient and/or healthcare staff injury.

- A CAUTION highlights a product reliability issue. ALWAYS comply with this information to prevent product damage.
- A **NOTE** supplements and/or clarifies procedural information.

### **Contact Information**

For additional information, including safety information, in-service training, or current literature, contact your Stryker sales representative or call Stryker customer service at 1-269-323-7700 or 1-800-253-3210. Outside the US, contact your nearest Stryker subsidiary.

# **Indications For Use**

The Stryker System 8 Dual Trigger Rotary Battery Powered Heavy Duty System is intended for use in the drilling, reaming, and decorticating of bone and other bone related tissue in a variety of surgical procedures. It is also usable in the placement of screws, wires, pins, and other fixation devices.

# Contraindications

None known.

# **Safety Directives**



- Before using this equipment, or any component compatible with this equipment, read and understand the instructions for use. Pay particular attention to safety information. Become familiar with the equipment before use.
- Only healthcare professionals trained and experienced in the use of this medical device should operate this equipment.
- The healthcare professional performing any procedure is responsible for determining the appropriateness of this equipment and the specific technique used for each patient. Stryker, as a manufacturer, does not recommend surgical procedure or technique.

- Upon initial receipt and before each use, operate the equipment and inspect each component for damage. DO NOT use any equipment if damage is apparent or the inspection criteria are not met. See the care instructions manual supplied with the handpiece.
- Upon initial receipt and before each use, clean and sterilize the equipment as indicated. See the care instructions manual supplied with the handpiece.
- DO NOT use this equipment in areas in which flammable anesthetics or flammable agents are mixed with air, oxygen, or nitrous oxide.
- Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment. Place this equipment into service according to the EMC information contained in this manual. Portable and mobile radio frequency (RF) communications equipment can affect the function of this equipment.
- ALWAYS lock the handpiece triggers before installing or removing attachments or accessories.

# Accessories



- Use only Stryker-approved electronic components and accessories. Failure to comply may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system.
- DO NOT modify any equipment without the authorization of the manufacturer.

#### NOTES:

- A variety of attachments are available for use with this handpiece. Each attachment has a specialized retainer for wires, pins, tools and/ or cutting accessories. See the instructions for use supplied with the attachment.
- For a complete list of accessories, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

The following Stryker-approved accessories are sold separately:

#### Attachments

| DESCRIPTION           | REF (SERIES) |
|-----------------------|--------------|
| Heavy Duty Rotary     | 8203-XXX-XXX |
| Handpiece Attachments | 7203-XXX-XXX |
|                       | 6203-XXX-XXX |

#### **Drill Bits**



 Upon initial receipt and before use, visually inspect the package for damage to confirm the integrity of the sterile barrier. Do not use the product if damage is apparent, the sterile barrier is compromised, or the package is unintentionally opened.

- DO NOT reuse, reprocess, or repackage a device that is intended for single use only.
  - A single use device may not withstand chemical, chemical vapor, or high temperature sterilization reprocessing.
  - Design features may make cleaning difficult.
  - Reuse may create a contamination risk and compromise structural integrity resulting in operational failure.
  - Critical product information may be lost during repackaging.

Failure to comply may lead to infection or cross infection and result in patient and/or healthcare staff injury.

**NOTE:** Sterile cutting accessories are sterilized by irradiation.

| DESCRIPTION | REF          |
|-------------|--------------|
| Drill Bits  | 0277-082-08X |
|             | series       |

### **Battery Packs**

| DESCRIPTION                          | REF          |
|--------------------------------------|--------------|
| System 8 Battery Packs               | 8212-000-000 |
|                                      | 8215-000-000 |
| SmartLife <sup>®</sup> Battery Packs | 7212-000-000 |
|                                      | 7215-000-000 |
| SmartLife Non-sterile                | 7126-110-000 |
| Batteries                            | 7222-110-000 |
| SmartLife Aseptic Housings           | 7126-120-000 |
|                                      | 7222-120-000 |
| SmartLife Transfer Shields           | 7126-130-000 |
|                                      | 7222-130-000 |
| System 6 Battery Packs               | 6212-000-000 |
|                                      | 6215-000-000 |
| System 6 Aseptic Battery             | 6126-000-000 |
| Kits                                 | 6127-000-000 |

#### **Insert Trays**

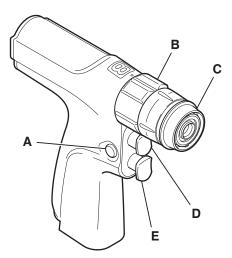
| DESCRIPTION  | REF          |
|--------------|--------------|
| Insert Trays | 7102-450-010 |
|              | 7102-452-010 |
|              | 7102-454-010 |
|              | 7102-458-010 |

# Features

**NOTE:** The Stryker System 8 Dual Trigger Rotary Handpiece (handpiece) is a component of the Stryker System 8 Battery Powered Heavy Duty System.

### Handpiece

The System 8 Dual Trigger Rotary Handpiece is battery powered and has two triggers and a function switch.



| Α | <b>Function Switch</b> – Locks one or both of the triggers. See the <i>Function Switch</i> section.              |
|---|--|
| В | Shift Collar – Sets the speed and torque. See the <i>Shift Collar</i> section.                                   |
| С | Attachment Collar – Retains the attachment in the handpiece.   |
| D | <b>Reverse Trigger</b> – Controls the variable speed operation of the handpiece in a counterclockwise direction. |
| E | <b>Forward Trigger</b> – Controls the variable speed operation of the handpiece in a clockwise direction.        |

**NOTE:** Press both triggers simultaneously to operate the handpiece in oscillate mode.

#### **Function Switch**

Forward Mode – Only the forward trigger is functional. The reverse trigger is locked to prevent inadvertent operation of the handpiece in a counterclockwise direction.



Forward/Reverse/Oscillate Mode – Both triggers are functional.



**Safe Mode** – Both triggers are locked to prevent inadvertent operation of the handpiece.

# Definitions

The symbols located on the equipment and/ or labeling are defined in this section or in the *Symbol Definition Chart*. See the *Symbol Definition Chart* supplied with the equipment.

| SYMBOL   | DEFINITION   |  |
|--|--|--|
|  | General warning sign                                   |  |
|  | Drill Mode   |  |
| REAM   | Ream Mode  |  |
| F/R 1 min /<br>4 min x 3<br>OSC 15s/15s<br>x 5 | Duty Cycle – See the<br><i>Specifications</i> section. |  |

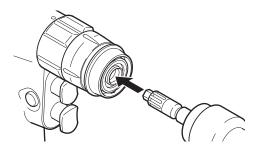
#### Shift Collar

| <b>Drill Mode</b> – Fast speed,<br>low torque operation |
|---|
| Ream Mode – Slow speed,<br>high torque operation        |

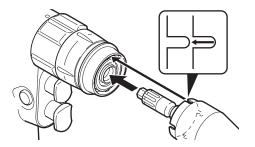
# Instructions

# To Install the Attachment and Accessory

- 1. Lock the handpiece triggers.
- 2. Insert the attachment into the handpiece until the attachment snaps into place.



**NOTE:** If the attachment has notches, align one of the notches with a tab under the attachment collar before insertion.

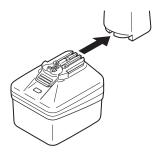


- Gently tug the attachment to make sure the attachment is securely locked in the handpiece.
- Install a wire, pin, tool, or cutting accessory as required. See the instructions for use supplied with the attachment.

### To Install the Battery Pack

**NOTE:** See the instructions for use supplied with the battery pack and/or battery charger for charging instructions and specifications.

- 1. Lock the handpiece triggers.
- Slide a fully charged battery pack into the handpiece until the battery pack snaps into place.



- Gently tug the battery pack to make sure the battery pack is securely locked in the handpiece.
- 4. Test the operation of the handpiece by unlocking and then depressing the trigger.

## To Operate the Handpiece



- ALWAYS lock the handpiece triggers when the handpiece is idle or when passing the handpiece to another person.
- Before operating the handpiece, ALWAYS gently tug the attachment and accessory to make sure the attachment is securely locked in the handpiece and the accessory is securely locked in the attachment.
- DO NOT grasp or touch any rotating component while the handpiece is operating.
- DO NOT change the position of the function switch while the handpiece is operating.
- DO NOT change the position of the shift collar while the handpiece is operating.
- DO NOT operate the handpiece in the drill mode position when a reamer attachment and/or accessory is installed in the handpiece.

- ALWAYS operate the equipment within the specified environmental condition values. See the Specifications section.
- ALWAYS follow the recommended duty cycle to prevent the equipment from overheating. See the *Specifications* section and/or the instructions for use supplied with the attachment.
- DO NOT apply excessive pressure, such as bending or prying, with the accessory.
  Excessive pressure may bend or fracture the accessory and result in tissue damage, loss of tactile control, and/or the ejection of accessory fragments at a high velocity.
- A wobbling attachment and/or accessory may cause bone or tissue damage or inaccurate wire or pin placement. If wobbling occurs, take corrective action as indicated in the *Troubleshooting* section.

#### CAUTIONS:

- DO NOT stall the handpiece. Failure to comply may damage the electric motor and/or battery pack. If the handpiece jams, release the trigger immediately. Remove any obstructions before continuing to operate the handpiece.
- If any power loss is experienced while using the handpiece, ALWAYS replace the battery pack with a fully charged battery pack. Failure to comply may result in a drained or damaged battery pack with a shortened life.

**NOTE:** See the *Features* section for mode descriptions.

- 1. Rotate the shift collar to the drill mode or ream mode position.
- Slide the function switch to the forward or forward/reverse/oscillate position.
- 3. Depress one of the pressure-sensitive triggers to operate the handpiece.

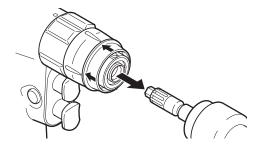
### To Remove the Battery Pack

- 1. Lock the handpiece triggers.
- 2. Depress the battery latch and slide the battery pack out of the handpiece.



# To Remove the Attachment and Accessory

- 1. Lock the handpiece triggers.
- 2. Remove the accessory from the attachment.
- 3. Pull the attachment collar back and remove the attachment from the handpiece.



# **Care Instructions**

For processing instructions and disposal/recycle information, see the care instructions manual supplied with the equipment.

# Troubleshooting

WARNING: DO NOT disassemble or service this equipment without the authorization of the manufacturer.

**NOTE:** For service, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

| PROBLEM   | CAUSE   | ACTION  |
|---|---|---|
| The handpiece does not operate or operates at a reduced speed.        | The battery pack is discharged.   | Use a Stryker battery charger to recharge the battery pack.   |
|   | The battery pack is expended.   | Replace the battery pack.   |
|   | The handpiece trigger is locked.  | Unlock the handpiece trigger.<br>See the <i>Features</i> section.   |
|   | The handpiece is damaged.   | Return the equipment to Stryker for repair.   |
| The handpiece operates but<br>the cutting accessory does not<br>move. | The attachment is not fully installed in the handpiece.                         | Remove and install the<br>attachment. Make sure the<br>attachment is securely locked in<br>the handpiece. |
|   | The shift collar is positioned<br>between the drill and ream<br>mode positions. | Fully rotate the shift collar to<br>either the drill mode or ream<br>mode position.                       |
|   | Excessive pressure is being applied to the cutting accessory.                   | Release the pressure and allow the cutting accessory to do the cutting.                                   |
|   | The handpiece is damaged.   | Return the equipment to Stryker for repair.   |

| PROBLEM   | CAUSE                             | ACTION   |
|---|-----------------------------------|--|
| The handpiece continues to operate after the trigger is released. | The handpiece is damaged.         | Depress the battery latch and<br>slide the battery pack out of<br>the handpiece. Return the<br>equipment to Stryker for repair.  |
| The equipment becomes unusually hot during use.                   | The duty cycle has been exceeded. | ALWAYS follow the<br>recommended duty cycle<br>to prevent the equipment<br>from overheating. See the<br><i>Specifications</i> section and/or<br>the instructions for use supplied<br>with the attachment.              |
|   | The handpiece is damaged.         | Return the equipment to Stryker for repair.  |
|   | The battery pack is damaged.      | Use a Stryker battery charger to<br>check the integrity of the battery<br>pack. See the instructions for<br>use supplied with the battery<br>charger for more information.<br>Replace the battery pack if<br>required. |

| PROBLEM  | CAUSE  | ACTION  |
|--|--|---|
| The attachment will not fit<br>or cannot be secured in the<br>handpiece. | The attachment and/or the distal<br>end of the handpiece contains<br>debris. | See the care instructions manual supplied with the handpiece.   |
|  | The attachment is damaged.   | Return the equipment to Stryker for repair.   |
|  | The handpiece is damaged.  | Return the equipment to Stryker for repair.   |
| The pin accessory cannot<br>be removed from the collet<br>attachment.    | The collet mechanism is jammed.  | Gently tap the side of the pin to<br>dislodge it from the collet.<br><b>CAUTION:</b> DO NOT attempt to<br>force the pin back through the<br>collet. |
|  | The collet is damaged.   | Return the equipment to Stryker for repair.   |

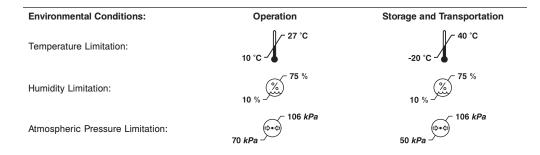
| PROBLEM   | CAUSE   | ACTION  |
|---|---|---|
| The attachment and/or accessory wobbles in the handpiece.   | The accessory is damaged.   | Inspect the accessory for damage and replace the accessory as required.   |
|   | The accessory is the wrong size for the attachment.   | Install a different accessory or attachment as required.  |
|   | The accessory extends too<br>far from the distal end of the<br>attachment, or is not properly<br>centered in the attachment.    | Remove and properly install the accessory. If wobble persists, return the handpiece and attachment to Stryker for repair. |
|   | A reamer attachment and/or<br>accessory is installed in the<br>handpiece and the shift collar is<br>in the drill mode position. | Rotate the shift collar to the ream mode position.  |
| The handpiece is noisy and/or vibrates.                     | The handpiece is damaged.   | Return the equipment to Stryker for repair.   |
| The handpiece experiences sporadic electrical interference. | Electrical noise is present.  | Turn off all electrical equipment not in use in the operating room.   |
|   |   | Relocate electrical equipment<br>and/or increase spatial distance<br>between electrical equipment.                        |
|   |   | Plug operating room equipment<br>into different operating room<br>outlets.  |

# **Specifications**

**WARNING:** ALWAYS consult any documentation that accompanies attachments and/or accessories for product-specific duty cycles and instructions for use.

**CAUTION:** ALWAYS store the equipment within the specified environmental condition values throughout its useful life.

| Model:                                     | System 8 Dual Trigger Rotary Handpiece (REF 8205-000-000)                               |                                       |  |
|--|---|---------------------------------------|--|
| Dimensions:                                | 150 mm [5.9 inch] height, 39 mm [1.5 inch] width, 154 mm [6.1 inch] length              |                                       |  |
| Mass:                                      | 1.04 kg [2.3 lb]  |                                       |  |
| Speed:                                     | 1200 rpm (drill mode), 270 rpm (ream mode)  |                                       |  |
|  | Forward and Reverse Modes Oscillate Mode  |                                       |  |
| Mode of Operation:                         | Non-continuous  | Non-continuous                        |  |
| Duty Cycle:                                | 1 minute on/4 minutes off, 3 times  | 15 seconds on/15 seconds off, 5 times |  |
| Rest Between Cycles:                       | 3 hours   | 1.5 hours                             |  |
| Applied Part(s):                           | The distal end of the handpiece and the attachment as defined by the manufacturer       |                                       |  |
| Maximum Temperature<br>of Applied Part(s): | Less than 51 °C [124 °F] as tested to the <i>Product Safety Certification</i> standards |                                       |  |
| Power Supply:                              | Internally powered. Refer to battery housing for voltage rating.                        |                                       |  |
| Ingress Protection:                        | IPX9 during cleaning and sterilization  |                                       |  |
| Equipment Type:                            | Type BF Applied Part  |                                       |  |



#### **Product Safety Certification**



Canadian Standards Association (CSA) International

#### Canadian Standards Association (CSA)

CAN/CSA-C22.2 No. 60601-1:14, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance; (IEC 60601-1:2005+A1:2012, MOD)

# American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI)

ANSI/AAMI ES60601-1:2005/(R) 2012, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance; Consolidated Reprint (2009/(R) 2012); Amendment 2 (2010/(R) 2012); Amendment 1 (2012)

#### **Product Safety Compliance**

#### International Electrotechnical Commission (IEC)

IEC 60601-1:2005, Ed: 3.1, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance; Corrigendum 1 (2006); Corrigendum 2 (2007); Amendment 1 (2012)

IEC 60601-1-2:2014 Ed: 4, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Electromagnetic Disturbances

IEC 60601-1-2:2007 Ed: 3, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Electromagnetic Compatibility

IEC 60601-1-6:2010+ A1:2013 Ed. 3.1, Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Usability

IEC 62366-1:2007+ A1:2014 Ed 1.1, Medical Devices - Part 1: Application of Usability Engineering to Medical Devices

#### European Committee for Electrotechnical Standardization (CENELEC)

EN 60601-1:2006+A12:2014, Ed: 3.1, *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance;* IEC Corrigendum 1 (2006); IEC Corrigendum 2 (2007); CENELEC Corrigendum (2010); CENELEC Amendment A11 (2011); IEC Amendment 1 (2013); IEC Corrigendum 3 (2014); CENELEC Amendment A12 (2014)

### **Electromagnetic Compatibility**

| Guidance and manufacturer's declaration - electromagnetic emissions  |            |  |
|--|------------|--|
| The System 8 Dual Trigger Rotary Handpiece (REF 8205-000-000) is intended for use in the electromagnetic<br>environment specified below. The customer or the user of the System 8 Dual Trigger Rotary Handpiece (REF 8205-000-000) should assure that it is used in such an environment. |            |  |
| Emissions test   | Compliance | Electromagnetic environment - guidance   |
| RF emissions<br>CISPR 11   | Group 1    | The System 8 Dual Trigger Rotary Handpiece (REF 8205-000-<br>000) uses RF energy only for its internal function. Therefore, its RF<br>emissions are very low and are not likely to cause any interference in<br>nearby electronic equipment. |
| RF emissions<br>CISPR 11   | Class B    | The System 8 Dual Trigger Rotary Handpiece (REF 8205-000-<br>000) is suitable for use in all establishments, including domestic<br>establishments and those directly connected to the public low-voltage                                     |
| Harmonic<br>emissions<br>IEC 61000-3-2   | N/A        | power supply network that supplies buildings used for domestic purposes.   |
| Voltage<br>fluctuations/flicker<br>emissions   | N/A        |  |
| IEC 61000-3-3  |            |  |

| Guidance and manufacturer's declaration - electromagnetic immunity   |  |   |  |
|--|--|---|--|
| The System 8 Dual Trigger Rotary Handpiece (REF 8205-000-000) is intended for use in the electromagnetic<br>environment specified below. The customer or the user of the System 8 Dual Trigger Rotary Handpiece (REF 8205-000-000) should assure that it is used in such an environment. |  |   |  |
| Immunity test  | IEC 60601 test level   | Compliance level  | Electromagnetic environment -<br>guidance  |
| Electrostatic discharge<br>(ESD)<br>IEC 61000-4-2  | ±2, ±4, ±6, ±8 kV Contact<br>±2, ±4, ±8, ±15 kV Air  | ±2, ±4, ±6, ±8 kV<br>Contact<br>±2, ±4, ±8, ±15 kV<br>Air   | Floors should be wood, concrete or<br>ceramic tile. If floors are covered<br>with synthetic material, the relative<br>humidity should be at least 30%. |
| Electrical fast<br>transient/burst<br>IEC 61000-4-4  | ±2 kV at 100 kHz repetition<br>frequency for power supply<br>lines<br>±1 kV at 100 kHz repetition<br>frequency for input/output<br>lines | ±2 kV at 100 kHz<br>repetition frequency<br>for power supply<br>lines<br>±1 kV at 100 kHz<br>repetition frequency<br>for input/output lines | N/A  |
| Surge<br>IEC 61000-4-5   | ±0.5, ±1 kV line(s) to line(s)<br>±0.5, ±1, ±2 kV line(s) to<br>earth  | N/A<br>N/A  | N/A  |

| Immunity test   | IEC 60601 test level  | Compliance level | Electromagnetic environment -<br>guidance  |
|---|---|------------------|--|
| Voltage dips, short<br>interruptions and<br>voltage variations on | <5% $U_{\tau}$<br>(>95% dip in $U_{\tau}$ )<br>for 0.5 cycle  | N/A              |  |
| power supply input<br>lines<br>IEC 61000-4-11                     | 0% <i>U<sub>τ</sub></i><br>(100% dip in <i>U<sub>τ</sub></i> )<br>for 0.5 cycle at 0°, 45°, 90°,<br>135°, 180°, 225°, 270°, and<br>315° | N/A              |  |
|   | 0% $U_{\tau}$ (100% dip in $U_{\tau}$ )<br>for 1 cycle at 0°  | N/A              |  |
|   | 40% $U_{\tau}$ (60% dip in $U_{\tau}$ )<br>for 5 cycles   | N/A              | N/A  |
|   | 70% $U_{	au}$ (30% dip in $U_{	au}$ ) for 25 & 30 cycles at 0°  | N/A              |  |
|   | $<$ 5% $U_{	au}$<br>(>95% dip in $U_{	au}$ )<br>for 5 s   | N/A              |  |
|   | 0% <i>U<sub>7</sub></i><br>(100% dip in <i>U<sub>7</sub></i> )<br>for 5 s   | N/A              |  |
| Power frequency (50/<br>60 Hz) magnetic field<br>IEC 61000-4-8    | 3 A/m, 30 A/m   | 3 A/m, 30 A/m    | Power frequency magnetic<br>fields should be at levels<br>characteristics of a typical location<br>in a typical commercial or hospital<br>environment. |

NOTE:  $U_{\rm T}$  is the alternating current mains voltage prior to application of the test level.

| Guidance and manufacturer's declaration - electromagnetic immunity  |   |                                |   |
|---|---|--------------------------------|---|
| The System 8 Dual Trigger Rotary Handpiece (REF 8205-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 8 Dual Trigger Rotary Handpiece (REF 8205-000-000) should assure that it is used in such an environment. |   |                                |   |
| Immunity<br>test  | IEC 60601<br>test level   | Compliance<br>level            | Electromagnetic environment - guidance  |
| Conducted   | 3 Vrms  | N/A                            | IEC 60601-1-2 3rd Edition:  |
| RF<br>IEC 61000-<br>4-6   | 150 kHz<br>to 80 MHz<br>outside ISM<br>bands 80%<br>AM at 1 kHz   |                                | Portable and mobile RF communications equipment should be used<br>no closer to any part of the System 8 Dual Trigger Rotary Handpiece<br>(REF 8205-000-000), including cables, than the recommended<br>separation distance calculated from the equation applicable to the<br>frequency of the transmitter.  |
|   | 6 Vrms<br>150 kHz to<br>80 MHz in<br>ISM bands  |                                | Recommended separation distance:<br>$d=1.2\sqrt{P}$ 80 MHz to 800 MHz<br>$d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz   |
| Radiated RF   | Radiated RF 10 V/m 10 V/m<br>80 MHz to 80 MHz to  |                                | Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol: |
| 4-3   | 2.7 GHz<br>80 % AM at<br>1 kHz  | 2.7 GHz<br>80 % AM at<br>1 kHz | ((()) (Non-ionizing electromagnetic radiation)  |
| 3 V/m     3 V/m       80 MHz to     80 MHz to       2.5 GHz     2.5 GHz       80% AM at     80% AM at       1 kHz     1 kHz   | WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the System 8 Dual Trigger Rotary Handpiece (REF 8205-000-000) including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. |                                |   |

NOTE 1: At 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System 8 Dual Trigger Rotary Handpiece (REF 8205-000-000) is used exceeds the applicable RF compliance level above, the System 8 Dual Trigger Rotary Handpiece (REF 8205-000-000) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating System 8 Dual Trigger Rotary Handpiece (REF 8205-000-000).

<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

#### Recommended separation distances between portable and mobile RF communications equipment and the System 8 Dual Trigger Rotary Handpiece (REF 8205-000-000)

The System 8 Dual Trigger Rotary Handpiece (REF 8205-000-000) is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System 8 Dual Trigger Rotary Handpiece (REF 8205-000-000) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System 8 Dual Trigger Rotary Handpiece (REF 8205-000-000) as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output      | Separation distance according to frequency of transmitter<br>m |                   |                    |  |
|---------------------------|--|-------------------|--------------------|--|
| power of transmitter<br>W | 150 kHz to 80 MHz  | 80 MHz to 800 MHz | 800 MHz to 2.5 GHz |  |
|                           | N/A  | d=1.2√P           | d=2.3√P            |  |
| 0.01                      | N/A  | 0.12              | 0.23               |  |
| 0.1                       | N/A  | 0.38              | 0.73               |  |
| 1                         | N/A  | 1.2               | 2.3                |  |
| 10                        | N/A  | 3.8               | 7.3                |  |
| 100                       | N/A  | 12                | 23                 |  |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

| ES/DE/FR/IT/NL | 8205-001-710 |
|----------------|--------------|
| JA/ZH/KO       | 8205-001-720 |
| SV/DA/FI/PT/NO | 8205-001-730 |
| PL/EL          | 8205-001-750 |
| TR             | 8205-001-760 |
| RU             | 8205-001-770 |



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